



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date 7/11/2014

EPA Reg No./File Symbol 2596-RIR

Page 1 of 4


Applicant's/Registrant's Name & Address

The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688

Product

Hartz Reference #146

Ingredient Imidacloprid 9.1%/ Pyriproxyfen 0.46%

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	Product Identification and Composition	Submitted	The Hartz Mountain Corporation	own	
830.1600	Description of Materials Used to Produce the Product	Submitted	The Hartz Mountain Corporation	own	
830.1620	Description of the Production Process	Submitted	The Hartz Mountain Corporation	own	
830.1650	Description of the Formulation Process	Submitted	The Hartz Mountain Corporation	own	
830.1670	Discussion of Formation of Impurities	Submitted	The Hartz Mountain Corporation	own	
830.7100	Viscosity	Submitted	The Hartz Mountain Corporation	own	Self-Certification
830.1750	Certified Limits	Submitted	The Hartz Mountain Corporation	own	
830.1800	Enforcement Analytical Method	Submitted	The Hartz Mountain Corporation	own	
830.6302	Color	Submitted	The Hartz Mountain Corporation	own	Self-Certification
830.6303	Physical State	Submitted	The Hartz Mountain Corporation	own	Self-Certification
830.6304	Odor	Submitted	The Hartz Mountain Corporation	own	Self-Certification
830.6314	Oxidation/Reduction Chemical Incompatibility	Waiver Request	The Hartz Mountain Corporation	own	
830.6315	Flammability	Submitted	The Hartz Mountain Corporation	own	Self-Certification
830.6316	Explosibility	Waiver Request	The Hartz Mountain Corporation	own	
830.6317	Storage Stability	To be submitted	The Hartz Mountain Corporation	own	In process
Signature 			Name and Title David Jones/Manager Regulatory Affairs		Date 07/11/2014



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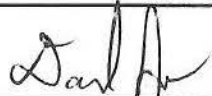
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Ingredient Imidacloprid 9.1%/ Pyriproxyfen 0.46%

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6319	Miscibility	Submitted	The Hartz Mountain Corporation	own	Self-Certification
830.6320	Corrosion Characteristics	To be submitted	The Hartz Mountain Corporation	own	In process
830.6321	Dielectric Breakdown Voltage	Waiver request	The Hartz Mountain Corporation	own	
830.7000	pH	Waiver request	The Hartz Mountain Corporation	own	
830.7300	Density/Relative Density/Bulk Density	Submitted	The Hartz Mountain Corporation	own	Self-Certification
870.1100	Acute Oral Toxicity	Submitted	The Hartz Mountain Corporation	own	
870.1200	Acute Dermal Toxicity	Submitted	The Hartz Mountain Corporation	own	
870.1300	Acute Inhalation Toxicity	Waiver request	The Hartz Mountain Corporation	own	
870.2400	Acute Eye Irritation	Submitted	The Hartz Mountain Corporation	own	
870.2500	Acute Dermal Irritation	Submitted	The Hartz Mountain Corporation	own	
870.2600	Skin Sensitization	Submitted	The Hartz Mountain Corporation	own	
870.7200	Companion Animal Safety Study	47089401	Bayer Healthcare	PAY	
870.7200	Companion Animal Safety Study	47089402	Bayer Healthcare	PAY	
870.7200	Companion Animal Safety Study	47089403	Bayer Healthcare	PAY	
Not specified	Pesticide Use-Product Performance (Efficacy)	43679503	Bayer Healthcare	OLD	

Signature 	Name and Title David Jones/Manager Regulatory Affairs	Date 07/11/2014
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Applicant's/Registrant's Name & Address The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688		Product Hartz Reference #146			
Ingredient Imidacloprid 9.1%/ Pyriproxyfen 0.46%					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Not Specified	Pesticide Use-Product Performance (Efficacy)	43679504	Bayer Healthcare	OLD	
Not Specified	Pesticide Use-Product Performance (Efficacy)	43679609	Bayer Healthcare	OLD	
Not Specified	Pesticide Use-Product Performance (Efficacy)	43679610	Bayer Healthcare	OLD	
Not Specified	Pesticide Use-Product Performance (Efficacy)	43794101	Bayer Healthcare	OLD	
Not Specified	Pesticide Use-Product Performance (Efficacy)	43794102	Bayer Healthcare	OLD	
95-9	Pesticide Use-Product Performance (Efficacy)	44256901	Bayer Healthcare	OLD	
95-9	Pesticide Use-Product Performance (Efficacy)	44256902	Bayer Healthcare	OLD	
95-9	Pesticide Use-Product Performance (Efficacy)	44256903	Bayer Healthcare	OLD	
Not Specified	Pesticide Use-Product Performance (Efficacy)	45425101	Bayer Healthcare	PAY	
Not Specified	Pesticide Use-Product Performance (Efficacy)	45425102	Bayer Healthcare	PL	
810.3300	Pesticide Use-Product Performance (Efficacy)	47109101	Bayer Healthcare	PAY	
810.3300	Pesticide Use-Product Performance (Efficacy)	47298201	Bayer Healthcare	PAY	
810.3300	Pesticide Use-Product Performance (Efficacy)	48240118	Bayer Healthcare	PAY	
86-1	Domestic Animal Safety	43679501	Bayer Healthcare	OLD	
86-1	Domestic Animal Safety	43679502	Bayer Healthcare	OLD	
Signature 			Name and Title David Jones/Manager Regulatory Affairs		Date 07/11/2014

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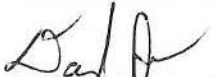
Applicant's/Registrant's Name &amp; Address

The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688

Product

Hartz Reference #146

Ingredient Imidacloprid 9.1%/ Pyriproxyfen 0.46%

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
86-1	Domestic Animal Safety	44157302	Bayer Healthcare	OLD	
870.7200	Companion Animal Safety	45097001	Bayer Healthcare	PAY	
870.7200	Companion Animal Safety	47089404	Bayer Healthcare	PAY	
870.7200	Companion Animal Safety	47089405	Bayer Healthcare	PAY	
870.7200	Companion Animal Safety	47089406	Bayer Healthcare	PAY	
870.7200	Companion Animal Safety	47924801	Bayer Healthcare	PAY	
Signature			Name and Title David Jones/Manager Regulatory Affairs		Date 07/11/2014



PROPOSED CAT DATA MATRIX CASS AND EFFICACY CITATIONS

July 11, 2014

MRID	Title	Guideline No.	Study Type	DER conclusion	Subm Date	DT Site	DT Pest	Misc.
43679501	Shmidl, J.; Arther, R. (1995) Acute Toxicity Evaluation for Dermal Treatment of Cats with Imidacloprid (Bay t 7391) Spot-On: Lab Project Number: TR-94D-010: 74579. Unpublished study prepared by Miles Inc. Animal Health DeSoto Research Facility. 19 p.	86-1	Domestic Animal Safety	This acute dermal study is classified as Acceptable when combined with another study (see below). ... However, when data are combined with the companion study in the cat (MRID 43679502), the information is considered useful. This satisfies the requirements for a domestic animal study in the cat.	6/7/1995	Laboratory Mammals	NA	11556-116; 11556-119
43679502	Shmidl, J.; Arther, R. (1995) General Safety Evaluation for Topical Use of Imidacloprid (Bay t 7391) Spot-On On Cats: Lab Project Number: TR-95F-006: 74591. Unpublished study prepared by Bayer Corp. DeSoto Research Facility. 41 p.	86-1	Domestic Animal Safety Study	See 43679501 above. When both cited, meets cat CASS data requirement.	6/7/1995	Laboratory Mammals	NA	11556-116; 11556-118
44157302	Shmidl, J.; Arther, R. (1996) General Safety Evaluation for Topical Use of Imidacloprid (Advantage) Spot-On on Kittens Eight Weeks of Age: Lab Project Number: 74747: TR-96F-006: 10332. Unpublished study prepared by Bayer Corp., DeSoto Research Facility. 45 p. Relates to L0000102.	86-1	Domestic Animal Safety Study	The study is considered acceptable and satisfies the draft guideline requirements (81-6) for a domestic animal safety study.	11/12/1996	8 wk old kittens	NA	9.1% Imid.
45097001	Abraham, A. (2000) Evaluation of the General Safety of 9.1% Imidacloprid with 0.9% Pyriproxyfen Spot-on Formulation in the Target Species, Adult Cats: Lab Project Number: 75122. Unpublished study prepared by Bayer Corporation. 139 p. {OPPTS 870.7200}	870.7200	Domestic Animal Safety Study	Toxicologically similar to MRID 47924801 which was deemed acceptable, see that entry elsewhere in this table	4/12/2000	Cats	NA	
47089401	Abraham, A. (2001) Evaluation of the General Safety of 9.1% Imidacloprid with 0.9% Pyriproxyfen Spot-on Formulation in the Target Species, 8-Week Old Kittens. Project Number: 75120, 150/851. Unpublished study prepared by Mobay Corp. and Bayer Corp. and Charles River Laboratories, Inc. 162 p.	870.7200	CASS		3/9/2007	8 week old kittens	NA	Support for 11556-126 and 11556-129
47089402	Abraham, A. (2001) Evaluation of the General Safety of 9.1% Imidacloprid with 0.9% Pyriproxyfen Spot-on Formulation in the Target Species, 8-Week Old Kittens. Project Number: 75120/1, 150/851. Unpublished study prepared by Mobay Corp. and Bayer Corp. and Charles River Laboratories, Inc. 8 p.	870.7200	CASS		3/9/2007	8 week old kittens	NA	Support for 11556-126 and 11556-129
47089403	Abraham, A. (2001) Evaluation of the General Safety of 9.1% Imidacloprid with 0.45% Pyriproxyfen Spot-on with 5.0% Water Blank Formulation in the Target Species, 8-Week Old Kittens. Project Number: 75190, 150/828. Unpublished study prepared by Mobay Corp. and Midwest Research Institute and Charles River Laboratories, Inc. 167 p.	870.7200	CASS		3/9/2007	8 week old kittens	NA	Support for 11556-126 and 11556-129

PROPOSED CAT DATA MATRIX CASS AND EFFICACY CITATIONS

July 11, 2014

MRID	Title	Guideline No.	Study Type	DER conclusion	Subm Date	DT Site	DT Pest	Misc.
47089404	Abraham, A. (2000) Evaluation of the General Safety of 9.1% Imidacloprid with 0.46 (W/W)% Pyriproxyfen Spot-on with 4.6% Water Blank Formulation at Three Times the Use Rate Volume in the Target Species, 8-Week Old Kittens.. Project Number: 75191/1, 150/937. Unpublished study prepared by Mobay Corp. and Bayer Corp. 8 p.	870.7200	CASS		3/9/2007	8 week old kittens	NA	Support for 11556-126 and 11556-129
47089405	Abraham, A. (2000) Evaluation of the General Safety of 9.1% Imidacloprid with 0.46% (W/W) % Pyriproxyfen Spot-on with 4.6% (W/W) Water Blank Formulation at Three Times the Use Rate Volume in the Target Species, 8-Week Old Kittens.. Project Number: 75191, 150/937. Unpublished study prepared by Mobay Corp. and Bayer Corp. 135 p.	870.7200	CASS		3/9/2007	8 week old kittens	NA	Support for 11556-126 and 11556-129
47089406	Abraham, A. (2001) Evaluation of the General Safety of 9.1% Imidacloprid with 0.45% Pyriproxyfen Spot-on with 5.0% Water Blank Formulation in the Target Species, 8-Week Old Kittens. Project Number: 75190/1, 150/828. Unpublished study prepared by Mobay Corp. and Midwest Research Institute and Charles River Laboratories, Inc. 8 p.	870.7200	CASS		3/9/2007	8 week old kittens	NA	Support for 11556-126 and 11556-129
47924801	Madsen, T. (2009) Evaluation of the General Safety of M880. Project Number: 152/141, S07648, 33714. Unpublished study prepared by Sinclair Research Center, Inc. 193 p.	870.7200	CASS	This companion animal safety study in male and female domestic shorthair kittens is acceptable/guideline and does satisfy the guideline requirement for a companion animal safety study (OPPTS 870.7200) in 54 - 57 day (8 week) kittens.	12/3/2009	8 wk old kittens	NA	11556-150






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830.6315	Flammability	Submitted	The Hartz Mountain Corporation	own	Self-Certification
830.6316	Explosibility	Waiver Request	The Hartz Mountain Corporation	own	
830.6317	Storage Stability	To be submitted	The Hartz Mountain Corporation	own	In process
Signature 			Name and Title David Jones/Manager Regulatory Affairs		Date 04/28/2014

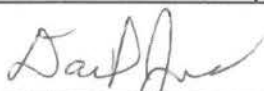


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830.7000	pH	Waiver request	The Hartz Mountain Corporation	own	
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870.1200	Acute Dermal Toxicity	Submitted	The Hartz Mountain Corporation	own	
870.1300	Acute Inhalation Toxicity	Waiver request	The Hartz Mountain Corporation	own	
870.2400	Acute Eye Irritation	Submitted	The Hartz Mountain Corporation	own	
870.2500	Acute Dermal Irritation	Submitted	The Hartz Mountain Corporation	own	
870.2600	Skin Sensitization	Submitted	The Hartz Mountain Corporation	own	
870.7200	Companion Animal Safety Study	47089401	Bayer Healthcare	PAY	
870.7200	Companion Animal Safety Study	47089402	Bayer Healthcare	PAY	
870.7200	Companion Animal Safety Study	47089403	Bayer Healthcare	PAY	
Not specified	Pesticide Use-Product Performance (Efficacy)	43679503	Bayer Healthcare	OLD	
Signature 	Name and Title David Jones/Manager Regulatory Affairs	Date 04/28/2014			





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Ingredient Imidacloprid 9.1%/ Pyriproxyfen 0.46%

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Not Specified	Pesticide Use-Product Performance (Efficacy)	43679504	Bayer Healthcare	OLD	<i>nothing new</i>
Not Specified	Pesticide Use-Product Performance (Efficacy)	43679609 ✓	Bayer Healthcare	OLD	<i>adult fleas on dog (was for dead)</i>
Not Specified	Pesticide Use-Product Performance (Efficacy)	43679610 ✓	Bayer Healthcare	OLD	<i>adult fleas on dog (was for dead)</i>
Not Specified	Pesticide Use-Product Performance (Efficacy)	43794101 ✓	Bayer Healthcare	OLD	<i>fleas/flea eggs on cat</i>
Not Specified	Pesticide Use-Product Performance (Efficacy)	43794102 ✓	Bayer Healthcare	OLD	<i>cat fleas on cat</i>
95-9	Pesticide Use-Product Performance (Efficacy)	44256901 ✓	Bayer Healthcare	OLD	<i>12 hr speed kill fleas</i>
95-9	Pesticide Use-Product Performance (Efficacy)	44256902 ✓	Bayer Healthcare	OLD	<i>lawn added on dog</i>
95-9	Pesticide Use-Product Performance (Efficacy)	44256903 ✓	Bayer Healthcare	OLD	<i>shampoo on dog</i>
Not Specified	Pesticide Use-Product Performance (Efficacy)	45425101	Bayer Healthcare	PAY	
Not Specified	Pesticide Use-Product Performance (Efficacy)	45425102	Bayer Healthcare	PL	
		<i>no LIO = 47190401</i>			

Signature <i>David Jones</i>	Name and Title David Jones/Manager Regulatory Affairs	Date 04/28/2014
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IMID CAT DATA MATRIX EFFICACY CITATIONS  
April 28, 2012

MRID	Title	Guideline No.	Study Type	Subm Date	DT Site	DT Pest	Misc.
43679503	Cunningham, J. (1995) Efficacy Evaluation of Bay t 7391 (Imidacloprid) 10% Solution Applied Dermal for Control of Fleas on Cats: Lab Project Number: MIC 194: 74571. Unpublished study prepared by AgResearch Consultants, Inc. 32 p.	Not Specified	Pesticide Use - Product Performance (Efficacy)	6/7/1995	Cats	Fleas	11556-116; 11556-118
43679504	Cruthers, L. (1995) Efficacy Evaluation of Bay t 7391 (Imidacloprid) 10% Solution Applied Dermal for Control of Fleas on Cats: Lab Project Number: PD-7391-95F-004: 74581. Unpublished study prepared by Professional Laboratory and Research Services, Inc. (PLRS). 46 p.	Not Specified	Pesticide Use - Product Performance (Efficacy)	6/7/1995	Cats	Fleas	11556-116; 11556-118
43679609	Cunningham, J. (1995) Efficacy Evaluation of Bay t 7391 (Imidacloprid) 10% Solution Applied Dermal for Control of Fleas on Dogs: Lab Project Number: 74572. Unpublished study prepared by AgResearch Consultants, Inc. 35 p.	Not Specified	Pesticide Use - Product Performance (Efficacy)	6/7/1995	Dogs	Fleas	11556-116; 11556-118
43679610	Cunningham, J.; Everett, R. (1994) Efficacy Confirmation of NTN 33893 (Imidacloprid) Solution Applied Dermal for Control of Fleas on Dogs: Lab Project Number: 74541: MID 194. Unpublished study prepared by AgResearch Consultants, Inc. 15 p.	Not Specified	Pesticide Use - Product Performance (Efficacy)	6/7/1995	Dogs	Fleas	11556-116; 11556-118
43794101	Hopkins, T.; Kerwick, C.; Woodley, I. (1995) Efficacy Evaluation of BAY t 7391 (Imidacloprid) 10% Solution Applied Dermal for Control of Adult Fleas and Flea Eggs on Cats: Lab Project Number: BH036/95: 74634: 95REPORT/AUSTRALI.DOC. Unpublished study prepared by Bayer Australia Ltd. 33 p.	None	Pesticide Use - Product Performance (Efficacy)	9/22/1995	Cat/Pets	Fleas	11556-116; 11556-118
43794102	Leibisch, A. (1995) Controlled Field Trials on the Efficacy and Tolerance of a Spot-On Formulation of Imidacloprid (BAY NTN 33893) 10% for Control of the Cat Flea (C. felis) in Domestic Cats: Lab Project Number: HVS 95-01: 74635: 95REPORT/74635.DOC. Unpublished study prepared by Institute of Parasitology, Hannover Vet School. 7 p.	None	Pesticide Use - Product Performance (Efficacy)	9/22/1995	Cat/Pets	Fleas	DER says data supports amend to 11556-116 and -118
44256901	Cruthers, L. (1997) Comparative Evaluation of How Quickly Advantage and Frontline (Fipronil) Top Spot Kill Fleas on Dogs: (final Report): Lab Project Number: 74800: PLRS 9665: 150.341. Unpublished study prepared by Professional Laboratory & Research Services, Inc. 51 p.	95-9	Pesticide Use - Product Performance (Efficacy)	4/17/1997	Dogs	Fleas	DER says data supports amend to 11556-116 and -118
44256902	Hopkins, T.; Woodley, I.; Gyr, P. (1997) Imidacloprid Topical Formulation: Larvicidal Effect Against Ctenocephalides felis in the Surroundings of Treated Dogs: (Revised Report): Lab Project Number: 74828: 97REPORT/ARTHER/HOPKINS.DOC. Unpublished study prepared by Bahrs Hill Research Station. 14 p.	95-9	Pesticide Use - Product Performance (Efficacy)	4/17/1997	Dogs	Fleas	DER says data supports amend to 11556-116 and -118
44256903	Cunningham, J. (1997) Evaluation of the Effects of Shampooing or Water Immersion on the Initial and Residual Efficacy of Advantage for Flea Control on Dogs: Lab Project Number: BD#296: 150.353: BD 295. Unpublished study prepared by AgResearch Consultants, Inc. 27 p.	95-9	Pesticide Use - Product Performance (Efficacy)	4/17/1997	Dogs	Fleas	PDMS lists 11556-116 and 11556-118
45425101	Mehlhorn, H.; Mencke, N.; Hansen, O. (1999) Effects of Imidacloprid on Adult and Larval Stages of the Flea Ctenocephalides felis after In Vivo and In Vitro Application: a Light and Electron-microscopy Study: Lab Project Number: 75292. Unpublished study prepared by Heinrich-Heine University of Dusseldorf. 17 p.	Not Specified	Pesticide Use - Product Performance (Efficacy)	6/6/2001	Indoor dwelling	Fleas	
45425102	Rust, M.; Mencke, N.; Hinkle, N. et al. (2001) The Influence of Imidacloprid on Adult Cat Flea Feeding. Suppl. Compend. Contin. Educ. Pract. Vet 23(4):18-21.	Not Specified	Pesticide Use - Product Performance (Efficacy)	6/6/2001	Indoor dwelling	Fleas	Public literature